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PATENT
Attorney Docket No. UM-04491

AG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: James R. Baker, Jr. *et al.*

Serial No.: 09/751,059

Group No.:

Filed: 12/29/00

Examiner:

Entitled: Antimicrobial Compositions And Methods Of Use

**INFORMATION DISCLOSURE
STATEMENT TRANSMITTAL**

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Dated: June 19, 2002

By:

Mary Ellen Waitz

Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

This Information Disclosure Statement is being filed before the issuance of a first Office Action and therefore, Applicants believe no fee is required but if the Commissioner deems otherwise, the Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: June 19, 2002


David A. Casimir

Registration No. 42,395

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
608/218-6900

FORM PTC-1449 (Modified)			U.S. Department of Commerce Patent and Trademark Office		Attorney Docket No.: UM-04491		Serial No.: 09/751,059	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR § 1.98(b))			Applicant: James R. Baker, Jr. <i>et al.</i>					
			Filing Date: 12/29/00		Group Art Unit:			
U.S. PATENT DOCUMENTS								
Examiner Initials	Cite No.	Serial / Patent Number	JUN 25 2002 Issue Date PATENT & TRADEMARK OFFICE 895	Applicant / Patente	Class	Subclass	Filing Date	
	1	5,618,840	04/08/90	Wright	514	549	05/18/95	
	2	5,547,677	08/20/96	Wright	424	401	05/20/94	
	3	5,549,901	08/27/96	Wright	424	401	10/13/94	
	4	5,700,679	12/23/97	Wright	435	238	06/07/96	
	5	5,662,957	09/02/97	Wright	426	605	05/03/96	
	6	5,510,104	04/23/96	Allen	424	94.4	06/02/95	
	7	5,103,497	04/07/92	Hicks	385	117	01/03/91	
	8	4,895,452	01/23/90	Yiourmas <i>et al.</i>	366	173	03/03/88	
	9	6,015,832	01/18/00	Baker, Jr., <i>et al.</i>	514	546	12/31/97	
	10	5,108,660	04/28/92	Michael	252	545	12/21/90	
	11	6,361,787	3/26/02	Shaheen <i>et al.</i>	424	406	5/27/98	
	12	6,348,187	2/19/02	Pan <i>et al.</i>	424	53	8/3/98	
FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS								
		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)								
	13	Alasri <i>et al.</i> , "Sporicidal properties of peracetic acid and hydrogen peroxide, alone and in combination, in comparison with chlorine and formaldehyde for ultrafiltration membrane disinfection." <i>Can. J. Microbiol.</i> 1993; 39: 52-60.						
	14	Barrett and Inglis "Growth purification and titration of influenza viruses." In: Mahy W.J. ed. Virology. a Practical approach. IRL. Press, 1985; 119-151. This reference is a book and is not being submitted at this time but if the Examiner requests the reference it will be submitted.						
	15	Baragi <i>et al.</i> , "Transplantation of transduced Chondrocytes protects articular cartilage from interdeukin 1 -induced extracellular matrix degradation." <i>J Clin Invest</i> 1995; 96: 2454-2460						
	16	Beauchamp <i>et al.</i> , "A critical review of the toxicology of glutaraldehyde." <i>Crit. Rev. Toxicol.</i> 1992; 22:143-174.						
	17	Berkelman <i>et al.</i> , "Emerging infectious diseases in the United States, 1993." <i>J Infect Dis.</i> 1994 Aug; 170(2):272-7						
	18	Burdon <i>et al.</i> , "Experimental infection of mice with <i>Bacillus cereus</i> : studies of pathogenesis and pathologic changes." <i>J. Infect. Dis.</i> 1967; 117: 307-316						
	19	Burdon and Wende. "On the differentiation of anthrax bacilli from <i>Bacillus cereus</i> ." <i>J. Infect. Dis.</i> 1960; 107: 224-234.						
	20	Chatlyne <i>et al.</i> , "A lipid emulsion with effective virucidal activity against H IV-1 and other common viruses." <i>Foundation for Retrovirology and Human Health</i> , 3rd Conference on Retroviruses and Opportunistic Infections, Washington D.C., U.S.A., 1996; Abstract #351. This reference is a book and is not being submitted at this time but if the Examiner requests the reference it will be submitted.						
	21	Dragon and Rennie "The ecology of anthrax spores: Tough but not invincible." <i>Can. Vet. J.</i> 1995; 36: 295-301						
	22	Drobniewski " <i>Bacillus cereus</i> and related species." <i>Clin. Microbiol Rev.</i> 1993; 6: 324-338						
Examiner:				Date Considered:				
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

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23	<i>EPA/DOE</i> <i>PTO/USPTO</i> <i>RECEIVED JUN 25 2002 C58</i> "Virus validation of plasma-derived products produced by Pharmacia, with particular reference to immuno Globulins." <i>Blood Coagulation and Fibrinolysis</i> 1994; 5 (Suppl. 3): S37-S44. This reference is a book and is not being submitted at this time but if the Examiner requests the referenc it will be submitted.				
24	Florence "Non-ionic surfactant vesicles: preparation and characterization." In: Gregoriadis G. ed. <i>Liposome Technology. Liposome Preparations and Related Techniques</i> . 2nd ed. Vol. 1. CRC Press, 1993. This reference is a book and is not being submitted at this time but if the Examiner requests the referenc it will be submitted.				
25	Foster and Johnstone "Pulling the trigger: the mechanism of bacterial spore germination." <i>MolecularMicrobiology</i> 1990;4:137-141.				
26	Franz <i>et al.</i> , "Clinical recognition and management of patients exposed to biological warfare agents." <i>JAMA</i> 1997; 278: 399-411				
27	Fritz <i>et al.</i> , "Pathology of experimental anthrax in'the rhesus monkey." <i>Lab. Invest.</i> 1995; 73: 691-702				
28	Goodman & Gilman's "The Pharmacological Basis of Therapeutics" Eds. Hardman <i>et al.</i> , 9th Edition, Publ. McGraw Hill, 1996; chapters 43 through 50. This reference is a book and is not being submitted at this time but if the Examiner requests the referenc it will be submitted.				
29	Graham <i>et al.</i> , "Characteristics of a human cell line transformed by DNA from human adenovirus type 5." <i>J Gen Viro</i> 1977; 36: 59-74				
30	Halvorson and Church, <i>Bacteriol Rev</i> 1957, 21:112				
31	Hamouda <i>et al.</i> , "Microbiocidal effects of liposome-like microemulsions on pathogenic Gram negative bacteria." In: American Society for <i>Microbiology</i> , 98th General Meeting, Atlanta, Georgia, U.S.A., 1998; Abstract A-52.				
32	Hamouda <i>et al.</i> , "A novel surfactant nanoemulsion with broad-spectrum sporicidal activity against Bacillus species". <i>Journal Infectious Disease</i> 1999. 180:1939-1949				
33	Hayden <i>et al.</i> , "Plaque inhibition assay for drug susceptibility testing of influenza viruses." <i>Antimicrob Agents Chemother</i> . 1980 17: 865-870				
34	Herlocher <i>et al.</i> , "Sequence comparison of A/IAA/6/60 influenza viruses: mutations, which may contribute to attenuation." <i>Virus Res.</i> 1996; 42:11-25				
35	Hermonat <i>et al.</i> , "The spermicide nonoxynol-9 does not inactivate papillomavirus." <i>Sexually Trans Dis</i> 1992; 19: 203-205.				
36	Hess <i>et al.</i> , "Epidermal toxicity of disinfectants." <i>Amer. J. Dent.</i> 1991; 4: 51-56.				
37	Hills, <i>J Gen Microbiol</i> 4:38,1950				
38	Horowitz <i>et al.</i> , "Solvent/detergent-treated plasma: a vi rus-in activated substitute for fresh frozen plasma." <i>Blood</i> 1992; 79: 826-831				
39	Huang <i>et al.</i> , "Antiviral activity of some natural and synthetic sugar analogues." <i>FEBS Letters</i> . 1991; 291: 199-202				
40	Ivins <i>et al.</i> , "Experimental anthrax vaccines: efficacy of adjuvants combined with protective antigen against an aerosol <i>Bacillus anthracis</i> spore challenge in guinea pigs." <i>Vaccine</i> 1995; 13: 1779-1784				
41	Jackson <i>et al.</i> , "PCR analysis of tissue samples from the 1979 Sverdlovsk anthrax victims: The presence of multiple <i>Bacillus anthracis</i> strains in 10 different victims." <i>PNAS</i> 1998; 95:1224-1229				
42	Karalvanova and Spiro RG. "Sulphation of N-linked oligosacchaddes of vesicular stomatitis and influenza virus envelope glycoproteins: host cell specificity, subcellular localization and identification of substituted saccharides." <i>Bioch J</i> 1998; 329: 511-518				
43	Lamanna and Jones "Lethality for mice of vegetative and spore forms of <i>Bacillus cereus</i> and <i>Bacillus cereus</i> -like insect pathogens injected intraperitoneally and subcutaneously." <i>J. Bact.</i> 1963; 85: 532-535				
44	Lamb and Krug "Orthomyxoviride: The viruses and their replication." In: Fields BN. Knipe DM. Howley PM. eds. <i>Fields Virology</i> , 3rd ed., Philadelphia Pennsylvania, U.S.A., Lippincott-Raven Publishers, 1996; 1353-1395.				
45	Lee "Review: in vitro spermicidal tests." <i>Contraception</i> 1996; 54: 131-147				
46	Lim and Chae "A simple assay for DNA transfection by incubation of the cells in culture dishes with substrates for beta-galactosidase." <i>Biotechniques</i> 1989; 7: 576-579.				
47	Lineaweaver <i>et al.</i> , "Topical antimicrobial toxicity." <i>Arch. Surg.</i> 1985; 120: 267-270.				
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	48	Maha and Igernini "The effect of nonionic detergent on dengue and Japanese encephalitis virus antigens in antigen detection ELISA and TRADEMA TM ELISA." <i>Southeast Asian J Trop Med Pub Health</i> 1997; 28: 718-722. This reference is a book and is not being submitted at this time but if the Examiner requests the reference it will be submitted.			
	49	Mammen et al., "Effective inhibitors of hemagglutination by influenza virus synthesized from polymers having active ester groups. Insight into mechanism of inhibition." <i>J Med Chem</i> 1995; 38: 4179-4190.			
	50	Mendel et al., "Oral administration of a prodrug of the influenza virus neuraminidase inhibitor GS 4071 protects mice and ferrets against influenza infection." <i>Antimicrob Agents Chemother</i> 1998; 42: 640-646.			
	51	Meselson et al., "The Sverdlovsk anthrax outbreak of 1979." <i>Science</i> 1994; 266:1202-1208.			
	52	Mobley "Biological warfare in the twentieth century: lessons from the past, challenges for the future." <i>Military Med.</i> 1995; 160: 547-553			
	53	Morgan "A brief review of formaldehyde carcinogenesis in relation to rat nasal pathology and human health risk assessment." <i>Toxicol Pathol</i> 1997; 25: 291-307			
	54	Mosmann J. <i>Immun. Methods</i> 1983, 65, 55-63 Mulder and Hers "Influenza." Wolter-Noordhoff Publishing, 1972.			
	55	O'Hagan "Recent advances in vaccine adjuvants for systemic and mucosal administration." <i>J Pharmacy Pharmacol</i> 1998; 50: 1 -10			
	56	Pile et al., "Anthrax as a potential biological weapon." <i>Arch. Intern. Med.</i> 1998; 158: 429-434			
	57	Portocala et al., "Immunolectrophoretic characterization of Sendai virus antigens." <i>Virologie</i> 1976; 27: 261-264			
	58	Russell "Bacterial spores and chemical sporcidial agents." <i>Clin. Micro</i> 1990; 3: 99-119			
	59	Schulze "Effects of glycolylation on the properties and functions of influenza virus hemagglutinin." <i>J Infect Dis</i> 1997; 176 (Suppl. 1): S24-28.			
	60	Shibata "Germination of inactivated spores of <i>Bacillus cereus</i> T. Effect of preincubation with L-alanine or inosine on the subsequent germination." <i>Japan. J. Microbiol.</i> 1976; 20: 529-535			
	61	Smith et al., "Dihydropyran carboxamides related to Zanamivir: a new series of inhibitors of influenza virus sialidases. I. Discovery, synthesis biological activity, and structure-activity relationships of 4-guanidino and 4-amino-4H-pyran-6-carboxamides." <i>J Med Chem</i> 1998; 41: 787-797			
	62	Titball and Manchee "Factors affecting the germination of spores of <i>Bacillus anthracis</i> ." <i>J. Appl. Bact.</i> 1987; 62: 269-273.			
	63	Waghorn and Goa, "Zanamivir." <i>Drugs</i> 1998; 55: 721-725.			
	64	Welkos and Friedlander "Pathogenesis and genetic control of resistance to the Steme strain of <i>Bacillus anthracis</i> ." <i>Microb. Path.</i> 1988; 4: 53-69			
	65	Welkos et al., "Differences in susceptibility of inbred mice to <i>Bacillus anthracis</i> " <i>Infect. Immun.</i> 1986; 51: 795-800			
	66	Yanagita, 1957, <i>Arch Mikrobiol</i> 26:329			
	67	Zeitlin et al., "Tests of vaginal microbicides in the mouse genital herpes model." <i>Contraception</i> 1997; 56: 329-335.			
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Filed: JUN 25 2002

Entitled: Antimicrobial Compositions And Methods Of

Use

Group No.:

Examiner:

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231, on June 19, 2002.

By: Mary Ellen Waite
Mary Ellen Waite

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- U.S. Patent 4,895,452
- U.S. Patent 5,103,497
- U.S. Patent 5,510,104
- U.S. Patent 5,547,677
- U.S. Patent 5,549,901
- U.S. Patent 5,618,840
- U.S. Patent 5,700,679
- U.S. Patent 5,547,677

- U.S. Patent 5,662,957
- U.S. Patent 5,108,660

- Alasri *et al.*, "Sporicidal properties of peracetic acid and hydrogen peroxide, alone and in combination, in comparison with chlorine and formaldehyde for ultrafiltration membrane disinfection." *Can. J. Microbiol* 1993; 39: 52-60.
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- Berkelman *et al.*, "Emerging infectious diseases in the United States, 1993." *J Infect Dis.* 1994 Aug; 170(2):272-7. Review.
- Burdon *et al.*, "Experimental infection of mice with *Bacillus cereus*: studies of pathogenesis and pathologic changes." *J. Infect. Dis.* 1967; 117: 307-316.
- Burdon and Wende. "On the differentiation of anthrax bacilli from *Bacillus cereus*." *J. Infect. Dis.* 1960; 107: 224-234.
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- Drobiewski "*Bacillus cereus* and related species." *Clin. MicrobioL Rev.* 1993; 6: 324-338.

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- Fritz *et al.*, "Pathology of experimental anthrax in'the rhesus monkey." *Lab. Invest.* 1995; 73: 691-702.
- Goodman & Gilman's "The Pharmacological Basis of Therapeutics" Eds. Hardman *et al.*, 9th Edition, Publ. McGraw Hill, 1996; chapters 43 through 50. This reference is a book and is not being submitted at this time but if the Examiner requests the referenc it will be submitted.
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- Hamouda *et al.*, "Microbiocidal effects of liposome-like microemulsions on pathogenic Gram negative bacteria." In: American Society for *Microbiology*, 98th General Meeting, Atlanta, Georgia, U.S.A., 1998; Abstract A-52.
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- Mobley "Biological warfare in the twentieth century: lessons from the past, challenges for the future." *Military Med.* 1995; 160: 547-553.
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- Mosmann J. *Immun. Methods* 1983, 65, 55-63
- O'Hagan "Recent advances in vaccine adjuvants for systemic and mucosal administration." *J Pharmacy Pharmacol* 1998; 50: 1 -10.
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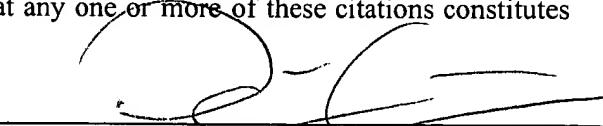
- Shibata "Germination of inactivated spores of *Bacillus cereus* T. Effect of preincubation with L-alanine or inosine on the subsequent germination." *Japan. J. Microbiol.* 1976; 20: 529-535.
- Smith *et al.*, "Dihydropyran carboxamides related to Zanamivir: a new series of inhibitors of influenza virus sialidases. 1. Discovery, synthesis biological activity, and structure-activity relationships of 4-guanidino and 4-amino-4H-pyran-6-carboxamides." *J Med Chem* 1998; 41: 787-797.
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- Waghorn and Goa, "Zanamivir." *Drugs* 1998; 55: 721-725.
- Welkos and Friedlander "Pathogenesis and genetic control of resistance to the Steme strain of *Bacillus anthracis*." *Microb. Path.* 1988; 4: 53-69.
- Welkos *et al.*, "Differences in susceptibility of inbred mice to *Bacillus anthracis*" *Infect. Immun.* 1986; 51: 795-800.
- Yanagita, 1957, *Arch Mikrobiol* 26:329
- Zeitlin *et al.*, "Tests of vaginal microbicides in the mouse genital herpes model." *Contraception* 1997; 56: 329-335.

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- U.S. Patent 6,015,832
- U.S. Patent 6,361,787
- U.S. Patent 6,348,187

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

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